IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff v. KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services For the State of Maine and ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine, Defendants.	)	Civil Action No. 00-157-B

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Defendants, Kevin Concannon, Commissioner of the Maine Department of Human Services, and Andrew Ketterer, Attorney General of the State of Maine, respectfully submit this memorandum of law in opposition to Plaintiff's motion for a preliminary injunction. For the reasons which are set forth below, the motion should be denied because the harm which will result to the defendants, and to the public interest, should the injunction issue outweigh the speculative harms claimed by the Plaintiff if the injunction is not issued. Furthermore, Plaintiff has failed to carry its burden of demonstrating a likelihood of succeeding on the merits of its Commerce Clause and Supremacy Clause challenges to the Maine Rx Program. Plaintiff has also failed to show that its members will be irreparably harmed without a preliminary injunction. Finally, Plaintiff's challenge to the "anti-profiteering" statute is nonjusticiable pursuant to Article III of the United States Constitution.

STATEMENT OF FACTS

The State of Maine enacted An Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter "the Act"), to further the overall health of Maine residents by making prescription drugs more affordable for citizens who lack a prescription drug benefit through public assistance or private insurance. 22 M.R.S.A. § 2681(1). The Act establishes the Maine Rx Program whereby Maine will collect rebates from those prescription drug manufacturer and labelers that agree to participate in the program, and will make reimbursements to retail pharmacies that participate in the program by offering discounted drug prices to qualifying residents of the State. 22 M.R.S.A. §2681.

The Act directs the Commissioner of the Department of Human Services (the "Department") to negotiate with those prescription drug manufacturers and labelers which participate in other publicly supported pharmaceutical programs in the State, in order to obtain rebates for the Maine Rx Program. 22 M.R.S.A. §2681(3). The initial goal, set by the statute, is for the Department to attempt to obtain Maine Rx Program rebates equal to or better than the rebate paid by manufacturers that participate in the Maine Medicaid program.

In the event that a prescription drug manufacturer or labeler does not agree to participate in the Maine Rx Program, the statute requires the Department to release the fact of that refusal to health care providers and to the public. 22 M.R.S.A. §2681(7). The statute also instructs that the Department "shall impose prior authorization requirements in the Medicaid program…as permitted by law, for the dispensing of prescription drugs provided by those manufacturer and labelers" that do not enter into Maine Rx rebate agreements. *Id.*

When a drug is subjected to a "prior authorization" requirement, the Medicaid program will reimburse for a prescription for such a drug only if the prescribing physician first requests and obtains the approval of the State Medicaid Administrator. The Medicaid statute itself contemplates that participating states may adopt "prior authorization" programs. 42 U.S.C. §1396r-s(d)(1)(A).

Pursuant to the rulemaking provisions of the Act, the Department has drafted administrative rules to govern the implementation of the "prior authorization" provisions of the Maine Rx Program. 22 M.R.S.A. § 2681 (14); 22 M.R.S.A. §3174-Y. These proposed

administrative rules provide, as follows:

> **Maine Rx Program**
> **Draft Proposed Rule for Prior Authorization Provision**
> **9/00**
>
> Drugs of non-participating drug manufacturers shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and state law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs.
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> **Maine Medical Assistance Manual, Section 80 (Pharmacy Services)**
> **Draft Proposed Rule for Prior Authorization Provision**
> **9/00**
>
> **Amend Rule 80.01-7 (new words are underlined).**
>
> Drug Utilization Review Committee means an advisory committee to the Medicaid Program, comprised of physicians and pharmacists, who are licensed to prescribe or dispense medications in Maine.
>
> **Proposed New Rule:**
>
> The Drug Utilization Review Committee shall consider and make the final determination regarding the clinical appropriateness of all prior authorization recommendations, including those concerning drug manufacturers who do not participate in the Maine Rx Program. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs.

On August 2, 2000, Commissioner Concannon commenced rebate negotiations with prescription drug manufacturers as required by the Act. Specifically, he presented to manufacturers the Department's proposed Maine Rx Program Rebate Agreement (the "Rebate Agreement"). *Concannon Aff.*, ¶ 4. The Rebate Agreement seeks Maine Rx Program rebates in an amount equal to the rebate which manufacturers electing to participating in the Medicaid program are required to provide to the State in connection with drugs dispensed through that

program. By the terms of the Agreement, the first Maine Rx Program rebate payments for drugs dispensed through the Maine Rx Program in the first calendar quarter of the program's operation will be due from participating manufacturers no earlier than September 30, 2001. Thus far, twenty-seven (27) prescription drug manufacturers have elected to participate in the Maine Rx Program by executing the Rebate Agreement. *Concannon Aff.*, ¶ *6.*

A separate section of the Act, 22 M.R.S.A. §2697, permits the Attorney General to bring civil actions against prescription drug manufacturers, distributors, and labelers that engage in illegal "profiteering" in prescription drugs. It is a violation of the profiteering statute if a manufacturer, distributor, or labeler "exacts or demands an unconscionable price; exacts or demands prices or terms that lead to any unjust or unreasonable profit; discriminates unreasonably against any person in the sale, exchange, distribution or handling or prescription drugs dispensed or delivered in the State; or intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions" of the Act. *Id.* There have been no enforcement proceedings brought or threatened by the Attorney General pursuant to the profiteering statute.

Plaintiff, the Pharmaceutical Research and Manufacturers of America, has brought an action seeking a declaratory judgment that the rebate provisions of the Maine Rx Program and the anti-profiteering statute violate the Commerce Clause of the United States Constitution, and that the "prior authorization" provision of the Maine Rx Program violates the Supremacy Clause of the Constitution. Plaintiff has moved for a preliminary injunction enjoining the enforcement of the Maine Rx Program's rebate and "prior authorization" provisions and of the

anti-profiteering statute. Defendants respectfully submit this memorandum of law in opposition to the motion for preliminary injunctive relief.

ARGUMENT

In its brief, Plaintiff accurately sets forth the test for a preliminary injunction which prevails in this (and other) circuits. In deciding whether to grant such extraordinary relief, the Court must consider: "(1) the likelihood of success on the merits; (2) the potential for irreparable harm in the injunction is denied; (3) the balance of relevant impositions, i.e., the hardship to the nonmovant if enjoined as contrasted with the hardship to the movant if no injuction issues; and (4) the effect (if any) of the court's ruling on the public interest." *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 15 (1st Cir. 1996).

Plaintiff fails to note, however, that in applying this test, the court will first seek to balance the harm which the plaintiff will suffer if the injunction does not issue against the balance of the harm to the defendant if it does issue in order to determine how much of a showing the plaintiff must make of a likelihood of success on the merits. If the balance tips strongly in his favor, the plaintiff need not show an absolute probability of success to obtain emergency interim relief. *Providence Journal Co. v. FBI*, 595 F.2d 889, 890 (1st Cir. 1979), *cited with approval in* *Marquis v. FDIC*, 965 F.2d 1148, 1155 (1st Cir. 1992). See generally *Washington Metropolitan Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841 (D.C. Cir. 1977), relying on the opinion of Judge Frank in *Hamilton Watch Co. v. Benrus Watch Co.*, 206 F.2d 738, 740 (2nd Cir. 1953). Conversely, the more the balance of harms tips against the plaintiff, the greater likelihood of success he must show, particularly if the public interest will also be harmed by the granting of the injunction.

In this case, the balance of harms tips strongly against the Plaintiff particularly because the public's health and welfare would be seriously and adversely affected if the preliminary injunction were to issue. Thus, the Plaintiff here must show a strong likelihood of success, which, also as is set forth more fully below, it has utterly failed to do. Accordingly, the motion for a preliminary injunction should be denied.

I. The Balance Of Harms, The Public Interest, And The Lack Of Irreparable Harm To The Plaintiff All Weigh Against Issuing A Preliminary Injunction.

A. The Harm To The Defendants And To The Public Interest If The Injunction Issues Is Substantial.

Not surprisingly, PhRMA treads lightly on two prongs of the test critical to the Court's analysis: a determination of the harms to the defendants that will occur should the injunction issue, and a consideration of where the public interest lies. Indeed, after correctly stating that the interests of the defendants and the public interest are identical, Plaintiff's sole argument on these prongs is a tautology: the statute is unconstitutional and the State can have no legitimate public interest in enforcing an unconstitutional statute. *See Plaintiff's Memorandum* at 23-24. The public interest furthered by the Maine Rx Program, and the continued harm which will be suffered by its beneficiaries should the preliminary injunction issue, ought not so readily be dismissed.

Expenditures for prescription drugs by the public are becoming an ever increasing component of total health care expenditures. While national health care expenditures experienced an average annual percentage growth of 5.5% from 1992 to 1997, prescription drug expenditures over the same period increased an average of 11.1% annually. Daniel Sherman, Amy Bradshaw, Myra Tanamor, Chris Topoleski, Barents Group, LLC, *Factors*

Affecting the Growth of Prescription Drug Expenditures, National Institute for Health Care Management Research and Education Foundation, July 9, 1999, at 1. As a result, expenditures for prescription drugs, as a percentage of total health care expenditures, increased from 5.6% in 1992 to 7.2% of health care expenditures in 1997. *Id.* In Maine, the net expenditures for outpatient drugs made by the State on behalf of Medicaid recipients increased by 9.5% from state fiscal year 1996-1997 to 1997-98, and by 20.3% from 1997-98 to 1998-99. *Concannon Aff.,¶ 12, exhibit C thereto.*

Not coincidentally, the price of prescription drugs are also increasing. According to one study, 64% of increased total expenditures on prescription drugs is the result of higher drug prices. *Factors Affecting the Growth of Prescription Drug Expenditures, supra,* at 15. Indeed, on a per prescription basis, drug expenditures in the Maine Medicaid program increased 22.8% from state fiscal year 1997 to 1999. *Concannon Aff.,¶ 12, exhibit C thereto.* The prices of the 50 prescription drugs most frequently used by the elderly increased more than four times the rate of inflation during 1998. Kathleen Haddad, *Hard to Swallow, Rising Drug Prices for America's Seniors,* Families USA Foundation, November 1999, at 2, 5.

Utilization of prescription drugs is also increasing. New drugs are being introduced to treat conditions which were previously not treatable by medication. More innovative and costly drug therapies are also replacing older, less expensive medications, as well as other more invasive procedures, as the favored course of treatment for a variety of conditions. *See* Stephen B. Soumerai, Sc.D., Dennis Ross-Degnan, Sc.D., *Inadequate Prescription-Drug Coverage for Medicare Enrollees – A Call to Action*, New England Journal of Medicine, Vol. 340, No. 9, March 4, 1999, at 723. In Maine, the increasing level of drug utilization is

reflected in a per person increase in the number of outpatient prescriptions filled in the Maine Medicaid program of 5.6% from state fiscal year 1997 to 1999. *Concannon Aff.,¶ 12, exhibit C thereto.* Many individuals in Maine have prescription drug coverage as part of either a privately or publicly funded health benefit program. Prescription benefit managers or private healthcare plans have the market position to negotiate lower drug prices with manufacturers on behalf of their insureds. *See* Soumerai, *supra*, 430 NEJM at 723. In the case of the major public program (Medicaid), manufacturers agree to remit rebates for drugs purchased on behalf of the program's recipients. Many individuals living in Maine, however, do not have prescription drug coverage as part of a health benefit plan, and indeed, many have no health benefit plan at all. These individuals pay cash for prescription drugs; and they pay the highest per-unit price for their drugs because, as individuals, they do not have the market power to negotiate a lower price with manufacturers. *See* Steven C. Tighe and Gregory B. Gilbert, *, Pharmaceuticals -- A Medicare Drug Benefit: May not be so Bad,* Merrill Lynch Report, June 23, 1999, at 6 ("[g]iven the high prices paid by Medicare recipients that currently pay out of pocket, this segment may be very (if not the most) profitable segment [for drug manufacturers]"). A few examples are both revealing and disturbing.

A study of the retail drug prices in Maine pharmacies found that the average retail price of the ten best-selling drugs used by the elderly was 86% higher than the price which is charged to the Federal government and to the drug manufacturers' most favored customers. Minority Staff Report, *Prescription Drug Pricing in the 1st Congressional District of Maine: Drug Companies Profit at the Expense of Older Americans,* Committee on Government Reform and Oversight, U.S. House of Representatives, prepared for Rep. Thomas H. Allen, October

9, 1998, at 18. Thus, the hardest hit appear to be the elderly. Although seniors constitute only about 13% of the national population, they account for approximate one-third of all prescriptions dispensed and 42% of total expenditures for prescription drugs. Amanda McCloskey, *Cost Overdose: Growth in Drug Spending for the Elderly*, Families USA Foundation, July 2000, at 2; *see also* Stephen B. Soumerai, Sc.D., Dennis Ross-Degnan, Sc.D., *Inadequate Prescription-Drug Coverage for Medicare Enrollees – A Call to Action*, New England Journal of Medicine, Vol. 340, No. 9, March 4, 1999, at 722. In the last eight years, the average number of prescriptions per elderly person grew by 45%, from 19.6 prescriptions per year in 1992, to 28.5 prescriptions in 2000. McCloskey, *Cost Overdose, supra* at 5. During that same period, the average cost per prescription for the elderly increased 48%, from $28.50 in 1992 to $42.30 in 2000. *Id* at 7. And the amount of prescription drugs purchased by people who must pay cash is significant. In Maine during 1996, for example, 48.1% of all drug expenditures were "out-of-pocket" expenditures. *Id.* at 10.

Faced with the highest prescription drug prices in the market, and without prescription drug coverage to pay for them, people respond in a variety of ways. Many travel to Canada, where they are charged, on average, 37% less than in Maine for the same medications. Alan Sager, Ph.D., Deborah Socolar, M.P.H, *Cutting Prescription Drug Spending By Paying Federal Supply Schedule Prices*, Northeast Legislative Association on Prescription Drug Pricing, Boston University School of Public Health, August 5, 2000, at 10; Diana Graettinger, *Border doctors offer prescription relief – Seniors go to great lengths for less expensive medications*, Bangor Daily News, Sept. 5, 2000, at A1. Others are forced to choose between buying food and buying medicine. *Prescription Drug Pricing in the 1st Congressional District*

of Maine: Drug Companies Profit at the Expense of Older Americans, supra, at 4, *citing Worthless Promises, Drug Companies Keep Boosting Prices,* Families USA Foundation, Mar. 1995, at 6 *and also citing A Status Report – Accessibility and Affordability of Prescription Drugs For Older Americans*, Senate Special Committee on Aging, 102d Congress., 2d Sess. 2(1992) (S. Rpt. 100). Some elderly patients will skip doses or split pills in an attempt to make their prescriptions last longer, or they will not fill their prescriptions at all. *Id. at 16. See also* Soumerai, *supra*, 340 NEJM at 723.

In Maine, there are an estimated 325,000 individuals who do not have prescription drug coverage. *Concannon Aff.*, ¶ *3.* The Maine Rx Program was intended to secure for these individuals fair drug prices so that they can purchase, on their own, the medication that they need. Maine's public interest in promoting the health of those citizens who are faced with the highest drug prices and who lack insurance coverage for prescription drugs is among the most weighty interests a State may have.[1] This public interest, and the harm which will continue to be suffered by the individuals for whom the Maine Rx Program was designed should the program be enjoined, outweigh whatever financial harms PhRMA speculates that its members might endure if the program is permitted to remain in force while this legal challenge to the statute is pending. For these reasons, the motion for a preliminary injunction should be denied.

[1] This goal is not only noble, but is financial as well. If a large segment of Maine's population cannot afford proper medication, the result will likely be increased illness. Eventually ill citizens may be unable to work and, without further resources, will tax already overburdened public assistance programs.

B. Plaintiff Has Failed To Demonstrate That Its Members Will Be Irreparably Harmed Without A Preliminary Injunction

PhRMA claims that its members are faced with a "Hobson's choice" – either they refuse to enter into Maine Rx Program rebate agreements and run the risk that their prescription drugs will be subjected to "prior authorization" requirements, or they agree to pay those rebates. Irreparable financial harm will purportedly result from either choice – if PhRMA's members' drugs are subjected to a "prior authorization" requirement, sales, market share and goodwill will suffer: and if the rebates are paid, they will be unrecoverable should the statute ultimately be struck down. *Plaintiff's Memorandum* at 22. Plaintiff's claims are speculative, and the magnitude of any possible financial loss is overstated.

The claim that implementation of the "prior authorization" provision of the Maine Rx Program will lead to drastic reductions of sales, market share, and goodwill is speculative because it is based upon a mistaken understanding of 22 M.R.S.A. §2681(7) and how that provision will be implemented. Title 22 M.R.S.A. §2681(7) states that a "prior authorization" requirement will be imposed upon a non-participating company's prescription drugs "as permitted by law." The Department of Human Services has construed the statutory language "as permitted by law" as referring to requirements of the Medicaid program. Specifically, the determination of whether a "prior authorization" requirement should be imposed for a particular drug will be guided by the principle that the Medicaid prescription drug program is designed to ensure that Medicaid recipients have access to "medically necessary" prescription drugs. *Concannon Aff.,* ¶ 9*; Clifford Aff.,* ¶ 8. Thus, no Medicaid recipient will be denied medically necessary medication. Indeed, the proposed administrative rules drafted by the Department will ensure that Medicaid recipients receive the particular drugs which they need,

because the "prior authorization" determination which will be made by the State's Medicaid Drug Utilization Review Committee, according to these principles of "medical necessity", as established by Medicaid law.[2] *Concannon Aff.,* ¶¶ 10-11*; Clifford Aff.,* ¶ 8. A manufacturer cannot reasonably assert that it is harmed if its medically "unnecessary" drug is not prescribed.

Plaintiff suggests, alternatively, that its members will suffer irreparable financial harm if they *do* elect to enter into Maine Rx Program rebate agreements. In this regard, Plaintiff points out, quite correctly, that in the event that the statute is ultimately struck down, Maine would be immune, pursuant to the Eleventh Amendment, from any subsequent suit brought by PhRMA's members seeking recovery of any rebates they had actually paid pursuant to the Maine Rx Program. *Plaintiff's Memorandum* at *21.* However, the Maine Rx Program does not begin until January 1, 2001, and, as is set forth in the Department's Maine Rx Program Rebate Agreement, no participating manufacturer is required to remit rebate payments for the first calendar quarter of the program until September 30, 2001. *Concannon Aff.,* ¶ 5. This litigation is likely to result in a final judgment in this court well before the first rebate payment

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[2] PhRMA also claims that "prior authorization" will harm patients. Aside from the fact that Plaintiff lacks standing to assert the interests of patients, it fails to prove its point. For example, SmithKline Beecham account executive, Dr. Scott Howell, points to his company's antibiotic, *Augmentin*. According to Howell, *Augmentin* "was recommended in national guidelines published by the CDC [Centers for Disease Control]" for use in treating "ear infections in children." If a prior authorization were required for *Augmentin*, says Howell, doctors would "switch [their] patients to less effective drugs" with the result that some children will "recover more slowly; and others will suffer complications needlessly." *Howell Decl., ¶ 7.*

A more complete, if not more forthright, explanation of what the CDC had to say about *Augmentin* can be found in Dr. Howell's company's annual financial report: "In January 1999, the U.S. Centers for Disease Control and Prevention published new recommendations for treating acute otitis media [ear infections] caused by resistant strains of *Sreptococcus pneumoniae.* The group recommended *Augmentin* as a *second line of defence* when amoxycillin has failed." *SmithKline Beecham 1999 Annual Report*,at 22 (emphasis added). *See also Richardson Aff.,* ¶ 8.

In other words, *amoxycillin,* and not *Augmentin,* is the drug of choice for treating the common ear infection. And while *Augmentin* may be appropriate for treating ear infections caused by bacteria resistant to amoxy cillin, a prior approval requirement for *Augmentin* could be justified to ensure that this far more expensive medication was not being prescribed as the first course of treatment in the typical case of a childhood ear infection.

is due, more than one year from now. Plaintiff's fear of being unable to recover rebate payments made before such a final judgment is therefore unfounded.

Furthermore, PhRMA has failed to quantify the expected, quarterly financial expense to any one of its members of paying the Maine Rx Program rebates requested by Commissioner Concannon. In fact, it is altogether possible that, due to the lower retail pharmaceutical prices Maine's uninsured will experience, the Maine Rx Program will cause the volume of sales of PhRMA's member companies' prescription drugs to increase. *See* Steven C. Tighe and Gregory B. Gilbert, *Pharmaceuticals -- A Medicare Drug Benefit: May not be so Bad,* Merrill Lynch Report, June 23, 1999, at 3. (suggesting that "when you either cut drug prices, provide a prescription benefit, or both, then volumes will go up with increased drug utilization").

Finally, twenty-seven (27) manufacturers have already elected to participate in the Maine Rx Program and have executed Maine Rx Rebate Agreements. *Concannon Aff.*, ¶ 6. The actions of these manufacturers undercuts any suggestion that the Maine Rx Program is onerous.

In sum, Plaintiff has failed to demonstrate that the so-called Hobson's choice its members face – the decision to participate or not to participate in the Maine Rx Program – will inexorably lead to financial harm of such a magnitude as to warrant a preliminary injunction.

II. Plaintiff Has Not Shown A Likelihood Of Success On The Merits Of Its Argument That The Maine Rx Program Violates The Commerce Clause.

At pages 10 through 13 of its Memorandum of Law, Plaintiff argues that the Maine Rx Program violates the dormant Commerce Clause of the United States Constitution because (1) it has an effect on extraterritorial transactions engaged in by the drug manufacturer-members of the Plaintiff association, and (2) it relies on an extraterritorial phenomenon – the federal "Medicaid

rebate amount" – to assist it in reaching its objective of reducing prescription drug prices for uninsured Maine consumers. Plaintiff does not make the most common kind of argument that a state statute violates the dormant Commerce Clause – that the statute discriminates against interstate commerce – because it cannot; the Maine Rx Program does not distinguish between instate and interstate commerce. Rather, Plaintiff relies on a line of cases in which the Supreme Court has held that, even if a state statute does not discriminate against interstate commerce, it may still violate the dormant Commerce Clause if it has "the 'practical effect' of regulating commerce occurring wholly outside that State's borders." *Healy v. The Beer Institute, Inc.*, 491 U.S. 324, 332 (1989). *See also Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573 (1986); *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935); L. Tribe, *American Constitutional Law*, §§ 6-8, 1074-80 (3rd ed. 2000). For the reasons which follow, the State suggests that neither of Plaintiff's concerns are valid since (1) the Maine Rx Program has neither the intention nor the effect of affecting out-of-state drug prices, and (2) the use of the federal Medicaid rebate amount by the Maine Rx Program as a non-binding factor to consider in achieving its in-state objectives is not the kind of economic parochialism which the dormant Commerce Clause is intended to inhibit. At the very least, Plaintiff has not shown a substantial likelihood that it will succeed on the merits of its Commerce Clause claim.

A. The Maine Rx Program Will Have No Unconstitutional, Extraterritorial Effect on Drug Prices.

At pages 10 and 11 of its brief, Plaintiff presents a simplistic argument that the dormant Commerce Clause prohibits a state from engaging in any kind of regulation which has any effect on any transaction that does not occur within the state. More specifically, Plaintiff argues that the effect of the Maine Rx Program is to affect transactions between its member manufacturers

and their distributors, none of which occurs within Maine, which it claims is forbidden by the line of Supreme Court authority cited above.[3]

The problem with Plaintiff's argument on this point is that it reads the Supreme Court cases much too broadly. In each of the three cases cited above, the state in question was attempting to achieve lower in-state prices for its consumers of milk or beer by tying those prices to prices charged by neighboring states (*Healy*) or any state (*Brown-Forman*). By contrast, the Maine Rx Program does not seek to accord to its uninsured consumers of prescription drugs the same price as such consumers might pay in some other state. Rather, the program seeks simply to lower the cost of the drugs to those consumers within Maine.

As the Supreme Court stated in *Brown-Forman*: "[A] State may seek to lower prices for its consumers, [so long as it does] not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, *supra*, 476 U.S. at 580, *quoted with approval* in *Healy v. The Beer Institute*, *supra*, 491 U.S. at 333. Thus, a state statute which simply seeks to lower prices for its own consumers does not violate the dormant Commerce Clause if it does not have the effect of affecting consumer prices in other states. The fact that the statute in question may have an effect on out-of-state transactions farther up the distribution chain is of no consequence. What counts is whether the state program has the intention or effect of improving the position of the state's consumers vis-à-vis those in other states.

To demonstrate that this is so, and that Plaintiff's reading of the Supreme Court authority is much too broad, the Court's attention is directed to the opinion of Judge Easterbrook in *K-S*

[3] Plaintiff supports this argument with a series of affidavits and declarations of employees of some of its member manufacturers that all of the manufacturer-distributor transactions of those manufacturers occur entirely out-of-state. *See* Declaration of Richard A. Feldman, Declaration of Thomas M. McPhillips, Declaration of Judith L. Tempel, and paragraphs 3 through 6 of the Affidavit of David Moules.

Pharmacies, Inc. v. American Home Products Corp., 962 F.2d 728 (7th Cir. 1992). In that case, the State of Wisconsin passed a statute which sought to eliminate price competition in prescription drugs sold within the state. Accordingly, it required that every wholesaler doing business within the state offer prescription drugs to every purchaser at the same price which it offered the drugs to its "most favored purchaser." The Seventh Circuit sustained the statute against the dormant Commerce Clause challenge because the Wisconsin Legislature made no attempt to affect retail prices outside of the state. As the Court observed, under the statute, "[s]o long as a seller charges the same price to all pharmacies in Wisconsin, it may do as it pleases in Minnesota or Micronesia." *Id*. at 730.

The same situation obtains with the Maine Rx Program. The state is not attempting to effect prices for prescription drugs in Minnesota or Micronesia, it is only attempting to lower those prices for a certain class of consumers within its borders. Naturally, as in the Wisconsin case, the state's action may have an effect upon entities further up the distribution chain, such as manufacturers. In Wisconsin, the price stabilization statute, which on its face applies only to wholesaler-retailer transactions, of course had an effect on wholesaler-manufacturer transactions out-of-state. But, as the Seventh Circuit held, the dormant Commerce Clause does not forbid state action simply because it has out-of-state consequences. The purpose of the Commerce Clause is to prevent states from using their powers to improve their competition positions in the national economy, a purpose not violated by either the Wisconsin or Maine statutes. Consequently, plaintiff has not carried its burden of showing that the Maine statute is likely to be invalidated simply because it has an effect on manufacturer-wholesaler transactions which may occur outside the state.

B. Plaintiff Has Not Carried Its Burden Of Showing That The Maine Rx Program's Use of the Federal Medicaid Rebate Amount Offends The Commerce Clause.

At pages 11 through 13 of its brief, Plaintiff makes a similar argument that the Maine Rx Program violates the dormant Commerce Clause because, in negotiating the amount that drug manufacturers are encouraged by the statute to pay to the state, the Commissioner of Human Services is directed to consider the federal Medicaid rebate amount as a guideline. Thus, once again, Plaintiff argues that the Maine RX Program violates the *Healy*/*Brown-Forman* line of cases because it is utilizing an out-of-state pricing "benchmark" (Plaintiff's word) with regard to state government transactions.

As the preceding discussion of the *Healy* and *Brown-Forman* cases made clear, the teaching of those cases is not that a state may take no action that has any effect on economic activity outside of the state, but only that it may take no action which seeks to improve the competitive position of its economy in the national economy. Once that is understood, Plaintiff's argument that the use of the federal Medicaid rebate amount in negotiating the amount of money which manufacturers are encouraged to pay to the state offends the Commerce Clause must fail. If the state had attempted to tie its prescription drug prices for uninsured consumers to those which prevailed in other states, such as the defendant states in *Healy* and *Brown-Forman* tried to do, the statute would, of course, be unconstitutional. Here, however, Maine has not adopted such a course; rather, it has directed its Commissioner to make use of a *national* standard in determining the amount of the rebate which the manufacturers are encouraged to pay. This approach, therefore, does not attempt to improve the state's competitive position vis-à-vis other states, but rather uses a national standard to assist the Commissioner in achieving the statute's

goals. It is difficult to see how, proceeding thusly, the statute could be seen to be serving an impermissible parochial interest.

Beyond this, it is worth noting that the statute does not in terms *require* the use of the federal Medicaid rebate amount. Section 2681(4)(B) provides only that "the Commissioner shall use the Commissioner's best efforts to obtain an initial rebate amount equal to or greater than [the Medicaid rebate]." Thus, the Maine Rx Program does not, as Plaintiff suggests, "*tie* [ ] prices in Maine to more paid in out-of-state transactions." Plaintiff's Memorandum at 12. It only encourages to the Commissioner to use the federal Medicaid rebate amount in negotiating a rebate for Maine consumers. For this additional reason, therefore, the reference to the Medicaid rebate amount in the statute is not unconstitutional because it uses that amount only as a guideline rather than a binding requirement on the Commissioner.

For the foregoing reasons, therefore, Plaintiff has not shown a likelihood of succeeding in its claim that the Maine Rx Program violates the dormant Commerce Clause. The program does not discriminate against interstate commerce on its face, nor does it have the effect of an unconstitutional interference with interstate commerce under the *Healy/Brown-Forman* line of cases. That being the case, there is no basis for further examination by the Court of the statute under such cases as *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). When a statute does not discriminate on its face against interstate commerce, and when it does not have an unconstitutional effect on interstate commerce, there is no basis for the Court to examine the law's benefits because there is no effect on interstate commerce against which to balance them. Thus, as the Seventh Circuit observed in *K-S Pharmacies*, once it has determined that a statute such as the Wisconsin law under examination there, or the Maine law at issue here, does not violate the *Healy/Brown-Forman* rule, "[n]othing remains for analysis under the balancing

procedure of *Pike*, . . ." so long as the justification for the statute is not "silly." *K-S Pharmacies v. American Home Products, supra*, 962 F.2d at 731. The protection of uninsured Maine consumers of prescription drugs against excessively high prices can hardly be considered "silly."

C. Even If The Maine Rx Program Has An Effect On Interstate Commerce, That Effect Is Incidental, And Is Outweighed By The State's Interest In Securing Affordable Prescription Drugs To Its Citizens Who Are Least Able To Afford Them.

If, notwithstanding the foregoing, the Court should somehow find that the Maine Rx Program does have an effect on interstate commerce, such a finding does not end the matter. The Court must then assess the degree to which interstate commerce is affected, and balance that against the interest which the State seeks to advance. The Supreme Court has held that incidental effects on interstate commerce are not constitutionally infirm when they are outweighed by the local benefits to be achieved by the regulation at issue. Specifically, in *Pike v. Bruce Church, Inc.* 397 U.S. 137, 142 (1970), the Court held that:

> Where the State regulates even-handedly to effectuate a legitimate local interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. *Huron Portland Cement Co. v. City of Detroit*, 362 U.S. 440, 443, 80 S.Ct. 813, 816, 4 L.Ed.2d 852. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

Plaintiff has not shown a likelihood of success under this balancing test. First, as demonstrated above, the impact which the plaintiff insists the program has on interstate commerce is truly incidental. It is beyond dispute that a state may regulate the retail price of goods sold within its borders. *K-S Pharmacies, Inc. v. American Home Products Corporation, supra.* Thus Maine

could have imposed price controls on drugs sold in Maine pharmacies, and such a measure would not implicate the Commerce Clause. In such a case, the pressure that such a retail price regulation would exert on upstream profits realized by manufactures in their transactions with wholesalers and distributors concerning drugs destined for the Maine retail market is precisely the same as the pressure on profits that PhRMA claims will occur due to implementation of the Maine RX Program. For these reasons, the profit pressure alleged by Plaintiff to result from the Maine Rx Program represents, at best, an incidental effect on interstate commerce.

In contrast, the state interest promoted by the Maine Rx Program is substantial. The Department has estimated that nearly 325,000 Maine citizens do not have access to prescription drugs through either public assistance programs or private insurance benefits. *Concannon Aff.* ¶ 3. These individuals are charged more for prescription drugs at the pharmacy than what the drug manufacturer's most favored customers pay. *See* Steven C. Tighe, *supra,* at 6. According to one study "[i]n the case of the five drugs with the highest sales to seniors, the average price differential between the price that would be paid by a senior citizen in the United States and the price that would be paid by the drug companies' most favored customer was 134%… This means that the average price that older Americans and other individuals pay for these drugs is more than double the price paid by the drug companies' favored customers, such as HMOs and the federal government." Minority Staff Report, *Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans*, Special Investigations Division, Committee on Government Reform, U.S. House of Representatives, November 9, 1999, at 6-7.

The individuals who are forced to pay these inflated retail prices come from the segments of Maine's society least able to afford such high premiums for necessary medication: elderly persons who survive on low, fixed incomes, and people employed by the small businesses which

operate on margins that simply do not permit the purchase of health plans with prescription drug benefits. Among these uninsured consumers of prescription drugs are individuals who choose not to buy groceries in order that they might afford to pay for their medication. Minority Staff Report, *Prescription Drug Pricing in the 1st Congressional District of Maine: Drug Companies Profit at the Expense of Older Americans,* Committee on Government Reform and Oversight, U.S. House of Representatives, prepared for Rep. Thomas H. Allen, October 9, 1998, at 4, *citing Worthless Promises, Drug Companies Keep Boosting Prices,* Families USA Foundation, Mar. 1995, at 6 *and citing A Status Report – Accessibility and Affordability of Prescription Drugs For Older Americans,* Senate Special Committee on Aging, 102d Congress., 2d Sess. 2(1992) (S. Rpt. 100). Also among these Maine consumers are individuals who further economize on their purchase of prescription drugs by taking less then the recommended dosage, no doubt with the effect that they receive reduced, in any, medical benefit from their purchase of their medications. *Id.* at 16. *See also* Soumerai, *supra,* 340 NEJM at 723. These are the individuals who fall through the cracks of the Medicaid prescription drug benefit and private insurance drug plans; and these are the individuals who are least able to afford the usurious premiums they are charged for their prescription drugs, as compared to the prices charged for those same drugs to individuals who are able to participate in publicly or privately funded prescription drug plans. Maine's interest in enhancing the ability of such citizens to purchase the drugs they need to survive, and to lead independent, fulfilling, and productive lives, greatly outweighs the unquantified, uncertain burden to manufacturer-wholesaler transactions, involving drugs destined for the Maine market, which happen to be consummated outside of Maine's borders.

In *General Motors Corp. v. Tracy,* 519 U.S. 278 (1997), the Supreme Court reaffirmed that a State may incidentally burden interstate commerce when promoting the health and safety

of its citizens. There, Ohio had imposed general sales and use taxes on natural gas purchases from all sellers except regulated public utilities that met the State's statutory definition of a "natural gas company." In a challenge by an out-of-state competitor of the public utilities the Court declared:

> State regulation of natural gas sales to consumers serves important interests in health and safety in fairly obvious ways, in that requirements of dependable supply and extended credit assure that individual buyers of gas for domestic purposes are not frozen out of their houses in the cold months.
>
> *Id.* at 306.

Certainly, the State of Maine's interest in securing affordable prescription medication for those citizens least able to afford it is every bit as weighty as the State of Ohio's interest in securing for its citizens a dependable supply, on extended credit, of natural gas so that they do not freeze in winter. Because this interest outweighs the impact on interstate commerce asserted by Plaintiff – an impact which is based solely on the situs of a wholesale transaction and which has no impact on similar wholesale transactions concerning drugs destined for other States – the Maine Rx Program does not violate the Commerce Clause. Accordingly, Plaintiff has failed to establish a strong likelihood of success under the *Pike* balancing test.

D. Plaintiff Is Not Likely To Succeed On The Merits Of Its Commerce Clause Claim Because The Maine Rx Program Is A Constitutionally Valid Exercise Of The State's Power To Use Its Market Position To Favor Its Citizens.

Finally, Plaintiff cannot carry its burden of showing a likelihood of success on the merits of its Commerce Clause claim because the Maine Rx Program was adopted in furtherance of Maine's prerogatives as a participant in the prescription drug market. The Supreme Court has held that, when a state acts as a market participant, it is not subject to the Commerce Clause. *Hughes v. Alexandria Scrap Corporation*, 426 U.S. 794 (1976); *Reeves, Inc. v. Stake*, 447 U.S.

429 (1980*); White v. Massachusetts Council of Construction Employers, Inc*. 460 U.S. 204 (1983); *South-Central Timber Development, Inc. v. Wunnicke,* 467 U.S. 82 (1984).

The State of Maine is a large purchaser of prescription drugs. In 1999, Maine spent $107,536,065, net of rebates, to purchase prescription drugs for 148,654 Medicaid recipients. The act of imposing "prior authorization" requirements, when otherwise permitted by law, on the drugs of manufacturers which elect not to participate in the Maine Rx Program is the sort of action which the state may undertake in order to use its relative position in the market to advance the interests of its citizens. Simply stated, in enacting the Maine Rx Program, Maine is merely attempting to leverage its market power as a large purchaser of drugs on behalf of some of its citizens to secure reasonable prices for other citizens of the State. Such an action is entirely outside of the reach of the Commerce Clause.

Hughes v. Alexandria Scrap Corporation, 426 U.S. 794 (1976) and *White v. Massachusetts Council of Construction Employers, Inc*. 460 U.S. 204 (1983) are instructive. In *Alexandria Scrap*, the State of Maryland, in an attempt to provide incentives for ridding the state of abandoned motor vehicles ("hulks"), agreed to pay a "bounty" for each hulk destroyed. The statutory scheme involved certain documentation requirements, which were far more burdensome for out-of-state processors of hulks than they were for processors located in Maryland. The Supreme Court held that this disparity, by which Maryland favored processors located in the state over out-of-state processors, was not subject to scrutiny under the Commerce Clause. It held that the Commerce Clause was not intended to limit a state's ability to favor its own citizens in connection with transactions in a market in which the state participates as a purchaser. *Alexandria Scrap,* 426 U.S. at 808. As the Court explained, the Commerce Clause was "designed in part to prevent trade barriers that had undermined efforts of the fledgling States

to form a cohesive whole following the Revolution." *Id.* at 807. It was not, however, designed to address instances where goods remain in a particular state, and do not flow into interstate commerce, where that movement or lack of movement is "in response to market forces, including that exerted by money from the State." *Id.* at 810. As the Court stated, "[n]othing in the purposes animating the Commerce Clause prohibits a State, in the absence of congressional action, from participating in the market and exercising the right to favor its own citizens over others." *Id*.

In *White,* the mayor of Boston issued an executive order requiring that all city funded construction projects be performed by a work force comprised of a least 50% of Boston residents. The Supreme Court held that the Commerce Clause imposed no barrier to such an arrangement because Boston was not engaging in regulation, but was simply using its power as a purchaser in the construction labor market. *Id*. at 210. Specifically, the Court held:

> [i]f the city is a market participant, then the Commerce Clause establishes no barrier to conditions such as these [the 50% resident requirement] which the city demands for its participation. Impact on out-of-state residents figures in the equation only after it is decided that the city is regulating the market rather than participating in it, for only in the former case need it be determined whether any burden on interstate commerce is permitted by the Commerce Clause.
>
> *White, supra,* 460 U.S. at 210.

As a market participant, the City of Boston was thus free to attempt to leverage its market position as a purchaser of construction services not only in selecting the contractors with which it would deal, but also in an attempt to dictate the residential makeup of the persons employed by such contractors.

Here, Maine is attempting to leverage its market power as a purchaser of prescription drugs in an attempt to achieve discounted drug prices for some of its citizens. Maine purchases

prescription drugs for one group of its citizens through Medicaid and through other state-funded drug plans. Prescription drugs produced by Plaintiff's members are among those which Maine buys through these public assistance programs. As a purchaser of these drugs, Maine is requesting that Plaintiff's members give rebates so that it can fund a program of discounted retail prices for the benefit of another segment of the State's population. The "prior authorization" provision of the Act, as set forth in 22 M.R.S.A. §2681(7), is nothing more and nothing less than the means by which Maine is attempting to use its market power to negotiate the rebates it has requested of drug manufacturers. Simply stated, Maine is using its power as a purchaser of prescription drugs to reduce its purchases of drugs manufactured by those manufacturers that decline to participate in the Maine Rx Program. It will reduce its purchases of drugs manufactured by non-participants by imposing, *as permitted by law*, a requirement that before the State will agree to reimburse a dispensing pharmacy for a prescription written for such drugs, a prescribing physician must request and obtain the authorization of the state's Medicaid Administrator. As the Supreme Court has held, Maine may attempt to use its market power as a purchaser to influence the market behavior of other participants in the market without implicating, much less offending, the Commerce Clause.

Plaintiff has not demonstrated, much less suggested, that the market participant exception has no applicability in this case. Therefore, for this additional reason, it has failed to carry its burden of demonstrating a likelihood of success on the merits of its Commerce Clause challenge to the Maine Rx Program. The motion for a preliminary injunction should thus be denied.

III. Plaintiff Has Not Shown A Strong Likelihood of Success On the Merits Of Its Claim That The Prior Authorization Provisions Of The Act Conflict With Federal Law In Violation Of The Supremecy Clause.

At pages 15 through 20 of its Memorandum of Law, Plaintiff argues that the Maine Rx Program violates the Supremacy Clause of the United States Constitution on the grounds that the use of a "prior authorization" requirement to encourage participation in the new program conflicts with, and it preempted by, the federal Medicaid statute. Again, Plaintiff fails to carry its burden of showing that it is likely to succeed on this theory.

"Preemption is strong medicine. Thus, although the power to preempt is absolute, its exercise is not lightly to be presumed. Rather, courts start with the assumption that the historic police powers of the States [are] not to be superseded by…[a] Federal Act unless that [is] the clear and manifest purpose of Congress. It follows inexorably that congressional intent stands at the base of all preemption analysis." *Massachusetts Association of Health Maintenance Organizations v. Ruthardt*, 194 F.3d 176 (1st Cir. 1999) (internal quotations and citations omitted).

Consequently, the first question to ask in evaluating any preemption claim is whether the Congress has expressly stated its intention to preempt state legislative authority. *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'm*, 461 U.S. 190, 203 (1983). Here, there is nothing in the language of the relevant federal law which suggests that Congress intended to preempt the states from adopting programs designed to lower drug prices for uninsured consumers. There is also nothing in the language of the relevant federal law which suggests that Congress intended to preempt the states from using the "prior authorization" mechanism as a means of encouraging manufacturers to participate in such new and innovative programs. Consequently, plaintiff does not argue that there is any express language in the

relevant federal law which evidences Congress's unmistakable intent to preempt the states in acting in this way. Plaintiff cannot make an "express preemption" argument for the simple reason that 42 U.S.C. § 1396r-8, the section of the Medicaid statute involving prescription drug benefits, contains no explicit, preemptive language.

In fact, 42 U.S.C. § 1396r-8 does precisely the opposite – it *grants* the States authority to adopt programs which impose "prior authorization" requirements on prescription drugs dispensed through the Medicaid program:

> 1396r-8(d) Limitations on coverage of drugs
>
> (1) Permissible restrictions
>
> > (A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

The requirements of "paragraph (5)" are the *only* requirements Congress deemed fit to impose on State prior authorization programs, and they are indeed quite modest:

> (5) Requirements of prior authorization programs
>
> > A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval—
> >
> > > (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
> > >
> > > (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

The Medicaid statute is a vast and complicated statute. And yet, the *language* of the only section of the Medicaid statute which is devoted to the Medicaid prescription drug benefit gives to the States broad authority to adopt prior authorization programs, imposing limits only on the speed and method of responding to a physician's request for a prior authorization. Thus, the language and structure of the statute itself, 42 U.S.C. § 1396r-8, is hardly an unmistakable expression of Congress's intent to preempt prior authorization programs such as Maine has here adopted. *Massachusetts Association of Health Maintenance Organizations*, 194 F.3d 176, 179 (1999). Indeed, the language and structure of the statute itself suggest just the opposite -- that Congress intended to give the states broad authority to adopt programs involving prior authorization requirements for the dispensing of drugs in the Medicaid program.

Plaintiff is thus reduced to making an argument that the Maine statute is preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'm, supra*, 461 U.S. at 204, *quoting Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Essentially, Plaintiff's claim is that by imposing a "prior authorization" requirement on the drugs of its members who do not participate in the Maine Rx Program, Maine may prevent certain people covered by Medicaid from receiving the drugs they need, thus frustrating the general purpose of the Medicaid statute. In support of this argument, plaintiff points to the legislative history of section 1396r-8, statements of *general* purpose appearing at the beginning of the Medicaid statute, and statements made by the Health Care Finance Administration (the agency responsible for administering the federal government's Medicaid responsibilities) in connection with administrative rules which it *proposed* in 1995. Plaintiff points to these sources all in an effort to persuade the Court that Maine violates the "purpose" of Medicaid when it

attempts to use its "prior authorization" authority as a tool to encourage drug manufacturers to help fund a discounted drug program for Maine citizens who do not qualify for Medicaid. What Plaintiff's mining of these sources uncovers, however, is at base nothing more than a series of statements supporting the rather unremarkable notion that the purpose of Medicaid, and the Medicaid prescription drug benefit in particular, is to ensure that Medicaid recipients receive prescription drugs which are "medically necessary."[4] Nothing in the Maine Rx Program, or its use of the "prior authorization" mechanism to encourage participation in the program, conflicts with this goal of the Medicaid Program.

As the affidavits of Timothy S. Clifford, M.D., and of Commissioner Concannon make clear, the Department of Human Services will not deny a single Medicaid recipient access to the safest and most efficacious prescription drug therapy indicated for their individual medical circumstances. *Concannon Aff.,* ¶ 9; *Clifford Aff.*, ¶ 8 The Department's administrative rules for the Maine Rx Program, and new rules governing the Medicaid Pharmacy Services Program, are both being designed to ensure that the Medicaid recipients receive the drugs they need. *Concannon Aff.,* ¶¶ 10-11. For instance, the Department's draft Maine Rx Program rules include the following provision:

> **Maine Rx Program**
> **Draft Proposed Rule for Prior Authorization Provision**
>
> Drugs of non-participating drug manufacturers shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and state law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs.

[4] "*Appropriate and medically* necessary means drug prescribing and dispensing that is in conformity with the predetermined standards established in accordance with [42 C.F.R.] § 456.703." 42 C.F.R. § 456.702. (Definitions) The "predetermined standards" which a State must adopt pursuant to the dictates of 42 U.S.C. § 456.703, are clinically based and scientifically valid standards for the prescribing and dispensing of prescription drugs.

Similarly, revisions to the Department's administrative rules governing Pharmacy Services in the Medicaid Program have been drafted so as to require that members of the Drug Utilization Review (DUR) Committee be either physicians or pharmacists who are licensed to prescribe or dispense medications in Maine. *Concannon Aff.,* ¶ ¶ 10-11. A draft amendment to the Medicaid Program rules also provides:

> **Maine Medical Assistance Manual, Section 80 (Pharmacy Services)**
> **Draft Proposed Rule for Prior Authorization Provision**
> **9/00**
>
> The Drug Utilization Review Committee shall consider and make the final determination regarding the clinical appropriateness of all prior authorization recommendations, including those concerning drug manufacturers who do not participate in the Maine Rx Program. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs.

In fact, the language of the Act requires the result sought to be achieved through these rules -- that the Maine Rx Program be implemented so as not to deny Medicaid recipients of medically necessary prescription drugs. Specifically, 22 M.R.S.A. § 2681(7) states, in relevant part, that "[t]he department shall impose prior authorization requirements in the Medicaid program under this Title, *as permitted by law*, for the dispensing of prescription drugs provided by those manufacturers and labelers [which do not enter into a Maine Rx rebate agreement]." (emphasis added). Plaintiff reads the phrase, *as permitted by law*, out of the statute. As the affidavits of Dr. Clifford and Commissioner Concannon demonstrate however, the Department of Human Services takes seriously its obligation to administer the new Maine Rx Program in a fashion which is consistent with its obligations as the administrator of Maine's Medicaid Program. Thus, the Maine Rx Program, both by the terms of the statute which establishes it, and

in the method by which the Department intends to administer it, does not stand as an obstacle to the purpose of the federal Medicaid law. Accordingly, Plaintiff has not, and cannot, demonstrate that it will succeed on the merits of their preemption claim.

IV. PhRMA'S Facial Challenge To The Anti-Profiteering Statute Does Not Present A Justiciable Case Or Controversy.

"It is fundamental that a court may only issue a declaratory judgment where there is an actual case or controversy within the meaning of Article III. To state a case or controversy under Article III plaintiffs must allege some threatened or actual harm which is real and immediate. A plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of a statute's operation or enforcement." *Interstate Food Processing Corporation v. State of Maine,* 826 F.Supp. 24, 25 (Me. 1993), *citing Babbit v. United Farm Workers Nat'l Union,* 442 U.S. 289, 298 (1979) (internal quotations omitted). Plaintiff's challenge to 22 M.R.S.A. §2697, the "anti-profiteering" statute, simply does not present a justiciable case or controversy under these standards.

Plaintiff claims that the prohibition on (1) exacting or demanding an unconscionable price; (2) exacting or demanding prices or terms that lead to any unjust or unreasonable profit; and (3) discriminating unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State each violate the Commerce Clause because, "on their face", they reach or effect or regulate out-of-state commercial transactions. *See Plaintiff's Memorandum* at 8. Plaintiff further claims that the prohibition on intentionally preventing, limiting, lessening or restricting the sale or distribution of prescription drugs in this State in retaliation for the provisions of the statute improperly regulates and

interferes with interstate commerce because it compels manufacturers "to do business in or directed toward the State through their existing channels of distribution." *Id.* at 13.

However, Plaintiff does not allege that its members desire to exact unconscionable prices for prescription drugs; that its members' prices will lead to an unjust or unreasonable profit; that its members desire to discriminate unreasonable against any person in connection with drugs dispensed or delivered in the State; or that its members desire to prevent, limit, lessen, or restrict the sale or distribution of their drugs in Maine in retaliation for passage of the Maine Rx Program. Moreover, Plaintiff does not claim that the defendants, or anyone else, has threatened to prosecute an action against any of its members pursuant to the provisions of 22 M.R.S.A. § 2697. In short, "[b]ecause Plaintiff has not made a preliminary showing of immediate adverse effect from the Maine statute[ ] in question, a determination of the scope and constitutionality of that legislation involves too remote and abstract an inquiry for the exercise of the judicial function." *Interstate Food Processing Corporation*, *supra*, 826 F.Supp. at 26.

Moreover, even if Plaintiff has presented a justiciable challenge to the "anti-profiteering" statute, nothing in the plain language of 22 M.R.S.A. §§2697(2)(A), (B), (C), and (D) supports the claim that the statute regulates interstate commerce or has an impermissible, "extraterritorial" reach. As demonstrated in Part II of this memorandum, the statute does not speak at all of transactions occurring outside of Maine. *See K-S Pharmacies, Inc. v. American Home Products Corporation*, 962 F.2d 728 (7th Cir. 1992) (refusing to read into the plain language of a drug pricing statute a broad meaning which would give the statute an extraterritorial, and unconstitutional, reach). Plaintiff's facial attack is therefore a nonstarter.

For this reason, Plaintiff is not likely to succeed on the merits of its challenge to the "anti-profiteering" statute. In addition, it cannot demonstrate irreparable harm in the form of an

imminent action against its members pursuant to 22 M.R.S.A. §2697. According, the motion for a preliminary injunction with respect to the "anti-profiteering" statute should also be denied.

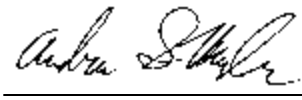
CONCLUSION

For the foregoing reasons, the defendants respectfully request that the motion for a preliminary injunction be denied.

Dated: Augusta, Maine
September 11, 2000

Respectfully submitted,

ANDREW KETTERER
Attorney General

by: 

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